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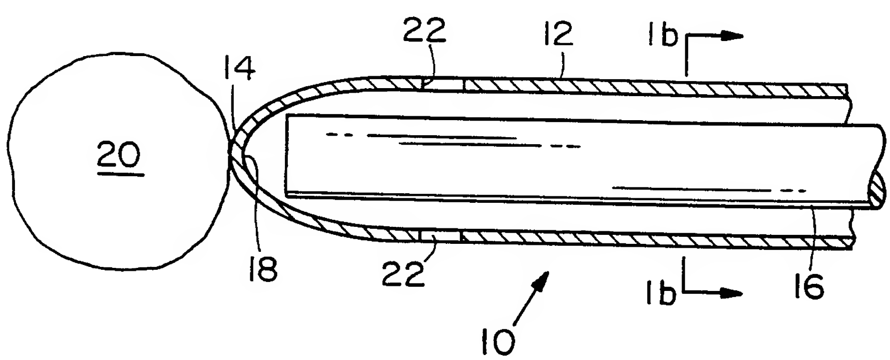

(57) Abstract

The catheter is used for generating localized shock waves. The shock waves may be used to destroy hard substances (20) within the human body such as calculi and calcific arterial plaque. The catheter is comprised of a tubular catheter body (12). A vibratile tip (14) is coupled to the tubular catheter body. It may be either loosely coupled or tightly coupled to the catheter body. In destroying the hard substances, the vibratile tip is positioned close to the hard substances. The inner surface (18) of the vibratile tip is then struck by energy sufficient to create a plasma at or near the inner surface. Irrigation is employed at this inner surface to contain the plasma that results from the excitation from the energy source. This creation of the plasma produces a shock wave that is translated into mechanical vibrations. The mechanical vibrations are propagated to the hard substance via the vibratile tip resulting in fragmentation of the hard substance. An energy source that may be used is laser energy. It may be transported to the inner surface of the vibratile tip via an optical fiber (16) that is disposed within the catheter body. Alternatively, electro-hydraulic energy may be used.

METHOD AND APPARATUS FOR FRAGMENTATION OF HARD SUBSTANCES

Background

Calculi, arterial plaque and other calcific deposits on body tissue pose a persistent and troubling problem to many patients. A number of different techniques have been devised to fragment such hard substances within the body. One prominent technique has been to use laser ablation to fragment the hard substances. An apparatus that fragments the hard substances in this manner is produced by the Candela Laser Corporation and is described in pending U.S. patent application "Use of Lasers to Break Down Objections", by Watson et al., Serial No. 07/041,158, filed April 22, 1987. In accordance with that design, a catheter is positioned so that it touches the target hard substance or at least is closely situated to the hard substance. A beam of laser energy is sent down the catheter via an optical fiber and strikes the hard substance. The excitation produced by the striking of the laser energy on the hard substance brings about fragmentation of the hard substance.

Summary of the Invention

A catheter generates a localized shock wave. It is comprised of a tubular catheter body that is coupled to a vibratile tip. This tubular catheter body has an outside diameter of preferably less than three millimeters. The inner surface of the

vibratile tip creates a plasma when it is exposed to an energy source. The plasma results in a shock wave that causes the vibratile tip to vibrate.

The energy source may be either a laser energy source or electrodes within a liquid medium. It is preferred that a fiber optic be disposed within the catheter body so as to carry the laser energy to the inner surface of the vibratile tip. In contrast, if the electrodes are used to generate the shock wave, it is preferred that the electrodes rather than a fiber optic be disposed within the catheter. This approach generates the shock wave by discharging one of the electrodes to the other electrode in a liquid medium of known conductivity.

It is desirable that the site where the energy strikes the inner surface of the vibratile tip be irrigated. To provide such irrigation, an irrigation means may be used. The liquid irrigant may be infused within the catheter or from a separate channel. A fluid that is known to perform irrigation well and pose no health risk to the patient is physiological saline solution. The irrigation confines the plasma so as to maximize the shock wave that is generated by the creation of the plasma, and it aids in removing the byproducts produced by the ablation of the inner surface of the vibratile tip.

This catheter may be used to destroy calculi within the human body. It may be also used to remove calcific arterial plaque. Since the preferable uses of this catheter involve insertion

into the human body, it is important that the catheter be easily inserted into the human body. To facilitate such easy insertion, it is preferred that the diameter of the tubular catheter body be less than three millimeters. It is also preferred that the vibratile tip of the catheter body be rounded so as to minimize the trauma involved in introducing the catheter into the body. Moreover, the catheter should be flexible so that it can be easily positioned in a tortuous vessel or duct. The vibratile tip may be employed in the body in one of two ways. First, it may be employed using an endoscope and secondly, it may be employed under fluoroscopic guidance.

A number of different designs may be used for the vibratile tip. In particular, the vibratile tip may be either loosely coupled to the tubular catheter body or tightly coupled to the catheter body. The loosely coupled approach provides for a higher level of vibration than the tightly coupled approach. The vibratile tip should also be of sufficient thickness so as to tolerate being struck by many successive laser pulses. The vibratile tip may be comprised of a number of different materials, included are tungsten, spring steel, elkonite, stainless steel, aluminum and copper alloys.

Brief Description of the Drawings

Figure 1a shows a longitudinal sectional view of a portion of a tightly coupled catheter of the

present invention and Figure 1b shows a cross-sectional view of the tightly coupled catheter.

Figure 2 shows an alternative tightly coupled catheter design with a plastic catheter body.

Figure 3 shows an alternative loosely coupled catheter design with an initiator cap embodiment.

Figure 4 shows an endoscope suitable for delivering the catheter to a site within a body.

Figure 5 shows an enlarged end view of the distal end of the endoscope.

Figure 6 shows a catheter employing the electro-hydraulic approach.

Detailed Description of the Preferred Embodiment

The preferred embodiment of the present invention concerns a catheter (such as 10 in Figure 1a) that is used to fragment hard substances 20 within the body. Specifically, in the preferred embodiment a catheter 10 is used for fragmentation of calculi and calcific arterial plaque. The catheter 10 fragments such hard substances 20 within the human body by generating a shock wave that is translated into mechanical energy at a vibratile tip 14 located at the end of catheter 10.

The acoustical shock wave that brings about the vibration at the vibratile tip 14 is produced by the generation of a plasma in the presence of water. This plasma is created at the inner surface 18 of the vibratile tip 14 when the vibratile tip 14 is subjected to energy from an energy source. The tip 14 is positioned so that it touches or is closely

situated to the hard substance 20; hence, when the tip 14 vibrates, the vibrations are passed on to the hard substance 20. These vibrations fragment the hard substances 20.

Figure 1a shows a preferred embodiment of the present invention. Figure 1b shows a cross-sectional view of this same embodiment. This catheter design is comprised of a tubular cylindrical body 12 that terminates into a rounded vibratile tip 14. As such, the vibratile tip 14 is tightly coupled to the catheter body 12. The shape of the vibratile tip 14 resembles a bullet and provides easy entry into the human body as well as maximum fragmentation capability. The catheter 10 also includes an optical fiber 16 disposed within it to carry laser energy to the inner surface 18 of the vibratile tip 14.

In this preferred embodiment, laser energy is sent from a distal end of the catheter 10 over the optical fiber 16 to the inner surface 18 of the vibratile tip 14. The laser energy is generated by a dye laser that can produce different energy outputs by changing the energy of the flash lamp that excites the dye. Lower energy outputs enhance the longevity of the catheter 10.

The laser pulses should have a pulse duration in the range of .05 microseconds to 10 microseconds. These pulse durations are generally sufficient to accomplish fragmentation of hard substances within the human body. Another parameter of concern is the energy level of the laser pulses. The energy level

of the laser output should be large enough to cause shock waves that lead to fragmentation. Pulse energy should, thus, be in the range of 20 millijoules to 500 millijoules. Typically, pulse energy in the range of 60 to 80 millijoules is sufficient. Higher pulse energy may be used, but it must be borne in mind that at too execessive of an energy level the pulses begin to consume the material at the inner surface 18.

A shock wave is produced by the absorption of the laser energy at the inner surface 18 of the vibratile tip 14. The laser energy heats, evaporates and ionizes the material of the inner surface 18 to such a great extent as to produce a plasma that is confined by the surrounding irrigation fluid. This plasma as confined by the surrounding fluid launches the shock wave which, in turn, propagates through the vibratile tip 14 in the form of mechanical vibrations. The vibrations are passed on to the target hard substance 20 resulting in fragmentation. To create a shock wave generating plasma, the intensity of the laser beam should be at least 20 millijoules.

The irrigant used to confine the plasma should be a liquid such as physiological saline solution that is not harmful to the human body. However, in some instances liquids such as water may be used. Irrigation may be provided by one of three methods. In the first method, the liquid is infused to the vibratile tip 14 via the catheter 10 containing the optical fiber 16. In the second method, the liquid

is infused via a separate channel in the catheter 10, and in a third method, the liquid is delivered through a separate channel in the endoscope. In all of these methods, an orifice is provided near the tip 14 that allows the irrigated liquid to enter or escape the catheter.

In order to achieve maximum fragmentation efficiency, the vibratile tip 14 must be configured efficiently so as to deliver the maximum possible mechanical shock to the hard substance 20 for a given quanity of energy delivered to the inner surface 18. One means of achieving this maximal fragmentation efficiency is to minimize the mass of the tip 14. This is because for a given amount of impulse generated by the laser energy, a low mass tip will experience the highest acceleration and thus, will impart the maximum mechanical shock to the hard substance. Moreover, selecting a material that readily absorbs the laser energy is helpful in maximizing the fragmentation efficiency. The choice of a material for the vibratile tip 14 must also, however, be dictated by the need to have a tip 14 that can withstand a large number of laser pulses, for a large number pulses may be required to completely fragment the hard substances 20. In other words, material resistant to laser ablation should be chosen. Possible materials include tungsten, elkonite and hardened steel alloys such as surgical stainless steel and spring steel. Alternatively, aluminum, copper alloys and certain ceramics may be used.

Another feature of the vibratile tip 14 that was discussed briefly above was the shape of the tip. As has already been mentioned, the tip is rounded so as to allow for easy insertion. Further, the shape of the tip also serves to maximize the peak pressure of the shock wave. By having a very small surface area in contact with the hard substance, the vibratile tip 14 increases the amount of pressure per unit of area and, therefore, has a better potential to fragment the hard substances 20.

Thus far, only one vibratile tip design has been discussed. This design may be fairly characterized as a design in which the vibratile tip is tightly held and is formed out of the catheter as opposed to being a distinct entity that is attached to the catheter body. Other designs are embodied within the present invention. A cap may be held by resilient material such as plastic, rubber or soft bellows. It may also be held loosely but in a captive manner.

In one alternative design, shown in Figure 2, the catheter 10 has a plastic sheath 36 as its body. an initiator cap 32 having a tip 14 is attached to the cylindrical plastic body 36 rather than having the tip 14 formed from the catheter 10. The initiator cap 32 includes barbs 38 to prevent the initiator cap 32 from being detached from the catheter 10 when the shock waves are generated. This design minimizes the mass of the vibrating surface and thus, increases the level of vibrations that are produced.

Another preferred embodiment utilizes an initiator cap 39 at the vibratile tip 14, but it, in contrast, is loosely coupled to a catheter 40 (see Figure 3). This embodiment operates in a manner similar to the other initiator cap 32 embodiment previously described. The primary difference between the two embodiments rests in how tightly the initiator cap 32 is coupled. In this embodiment, the initiator cap 39 is loosely coupled and supported by a spring 41 so as to provide greater room for movement. When the shock wave vibrates the initiator cap 32, it causes the initiator cap 32 to vibrate.

The catheter 10 may enter the body to be appropriately positioned near the hard substances 20 via a natural orifice such as the ureter, or it may enter percutaneously via a small incision. The catheter 10 is forwarded to the appropriate position using known techniques. One option is to employ the catheter 10 within an endoscope 24 such as the endoscope 24 shown in Figure 4. This endoscope design is discussed in pending U.S. patent application, "Endoscope with Tapered Shaft", Serial No. 07/307,321, by Cho _et_ _al._, filed February 6, 1989 and assigned to the Candela Laser Corporation. Three major components are disposed within the endoscope 24 (see Figure 5): a channel 26 which guides the catheter 10, an irrigation channel 30 and a coherent fiber optic bundle 28 for observing the inner body tissue and catheter 10. In addition,

illuminating noncoherent fiber optics 29 are provided to illuminate the fragmentation site.

Each of the above described options may be employed within a catheter 10 in the human body without an endoscope 24 such as shown in Figure 4. The catheter is radioopaque and is therefore easily guided using fluoroscopic techniques. As such, there is no need for an endoscope to assist in guidance.

Since in many instances, the catheter 10 is to be introduced into human organs and tissues having tight cavities, it is desirable to minimize the diameter of the catheter 10. In particular, it is desirable to have the catheter 10 have a diameter of less than three millimeters. In the preferred embodiment, the catheter 10 is approximately one millimeter in diameter. Thus, the fiber should be less than 600 microns in diameter. The length of the catheter 10 may vary. The length selected is primarily dependent on the application for which the catheter is being used.

Laser energy is not the only energy source that may be employed to generate a shock wave; electro-hydraulic energy may also be utilized. Specifically, two electrodes 42 and 44 may be disposed within the catheter 10 that are irrigated with a fluid of a known electrical conductivity as shown in Figure 6. To generate the shock wave, an electrical voltage pulse is applied to the electrodes 42. An electrical discharge is, thus, generated. Fluid in the spark path is immediatley

vaporized causing cavitations. When this occurs, high amplitude shock waves are generated in the fluid medium. These shock waves are transmitted to the vibratile tip 14 which, in turn, produces fragmentation of the hard substances 20.

The above methods have several advantages over the direct application of electro-hydraulic or pulsed laser energies to hard substances. The advantages include a possibility of more efficient fragmentation and the ability to fragment in cases where direct application of laser energy or electro-hydraulic energy is not effective. Moreover, this method also eliminates the direct exposure of tissue to laser energy or electro-hydraulic energy which may damage soft tissues.

While the invention has been particularly shown and described with reference to preferred embodiments thereof, it will be understood by those skilled in the art that various changes in form and details may be made without departing from the spirit and scope of the invention as defined in the appended claims.

CLAIMS

1. A catheter comprising:

   a tubular catheter body having a distal end;

   a vibratile tip at the distal end of the catheter body; and

   an energy source for creating a plasma on a back surface of the vibratile tip to cause the vibratile tip to vibrate.

2. A catheter as recited in Claim 1 wherein the catheter is readily insertable into human body cavities.

3. A catheter as recited in Claim 1 or 2 wherein the catheter is made of a flexible material.

4. A catheter as recited in Claim 1, 2 or 3 wherein the catheter is within an endoscope.

5. A catheter as recited in any preceding claim wherein the energy source is a laser which transmits through an optical fiber which extends through the catheter.

6. A catheter as recited in any of Claims 1-4 wherein the energy source is two electrodes.

7. A catheter as recited in any preceding claims wherein the vibratile tip is loosely coupled to the tubular catheter body.

8. A catheter as recited in Claim 7 wherein the vibratile tip is coupled through a spring.

9. A catheter as recited in any of Claims 1-6 wherein the vibratile tip is a cap coupled to the catheter body.

10. A catheter as recited in any preceding claim wherein the vibratile tip is tightly coupled to the tubular catheter body.

11. A catheter as recited in any preceding claim further comprising an irrigation means for providing fluid to an area where energy from the energy source strikes the back surface of the catheter body so as to contain a plasma to cause a shock wave that causes the vibratile tip to vibrate.

12. A catheter as recited in any preceding claim wherein the diameter of the tubular catheter body is less than 3 millimeters.

13. A method of generating localized shock waves comprising the steps of:

a) providing a catheter having a tubular body that is coupled to a vibratile tip;

b) striking an inner surface of the vibratile tip with energy from an energy source to create a plasma that generates a shock wave; and

c) irrigating the inner surface of the vibratile tip so as to contain the plasma and to assist in propagation of the shock wave to the vibratile tip.

14. A method as recited in Claim 13 where the energy source is a laser.

15. A method as recited in Claim 13 wherein the energy source is two electrodes.

16. A method as claimed in Claim 13, 14 or 15 wherein the vibratile tip is loosely coupled to the tubular catheter body.

17. A method as claimed in Claim 16 wherein the vibratile tip is coupled through a spring.

18. A method as claimed in Claim 13, 14 or 15 wherein the vibratile tip is a cap coupled to the catheter body.

19. A method as claimed in Claim 13, 14 or 15 wherein the vibratile tip is tightly coupled to the tubular catheter body.

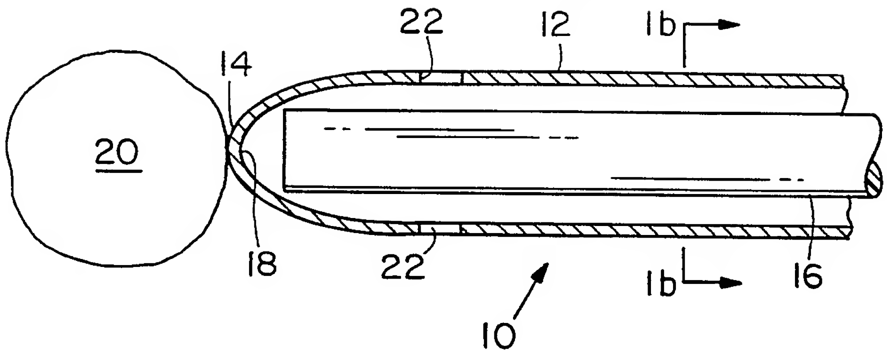

Fig. 1a

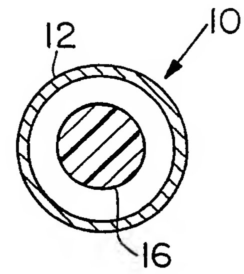

Fig. 1b

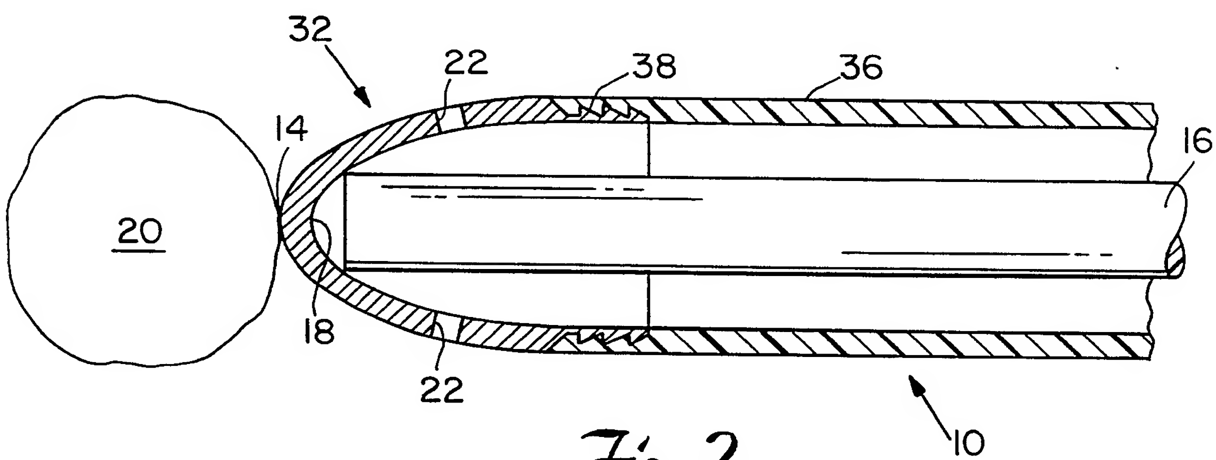

Fig. 2

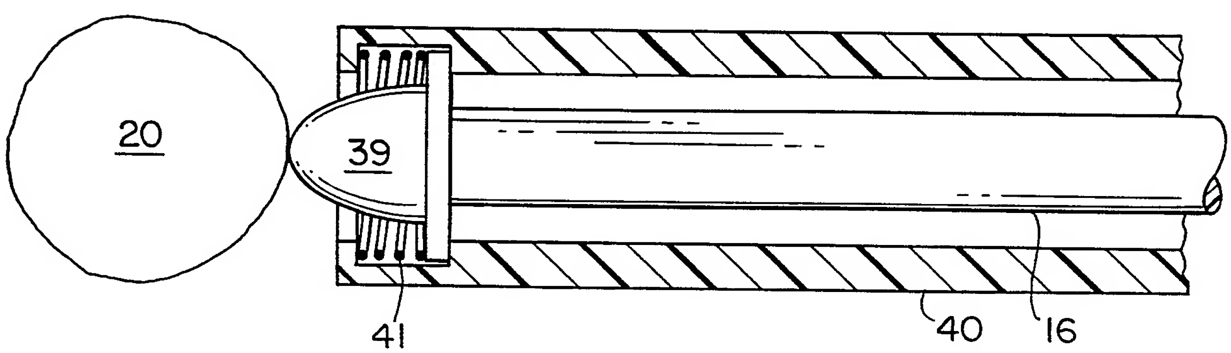

Fig. 3

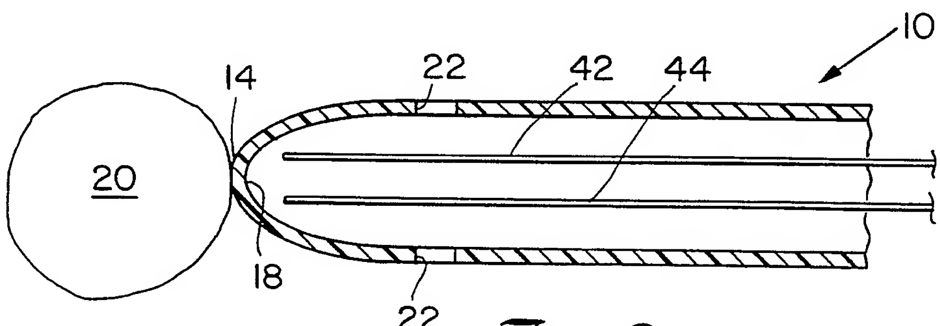

Fig. 6

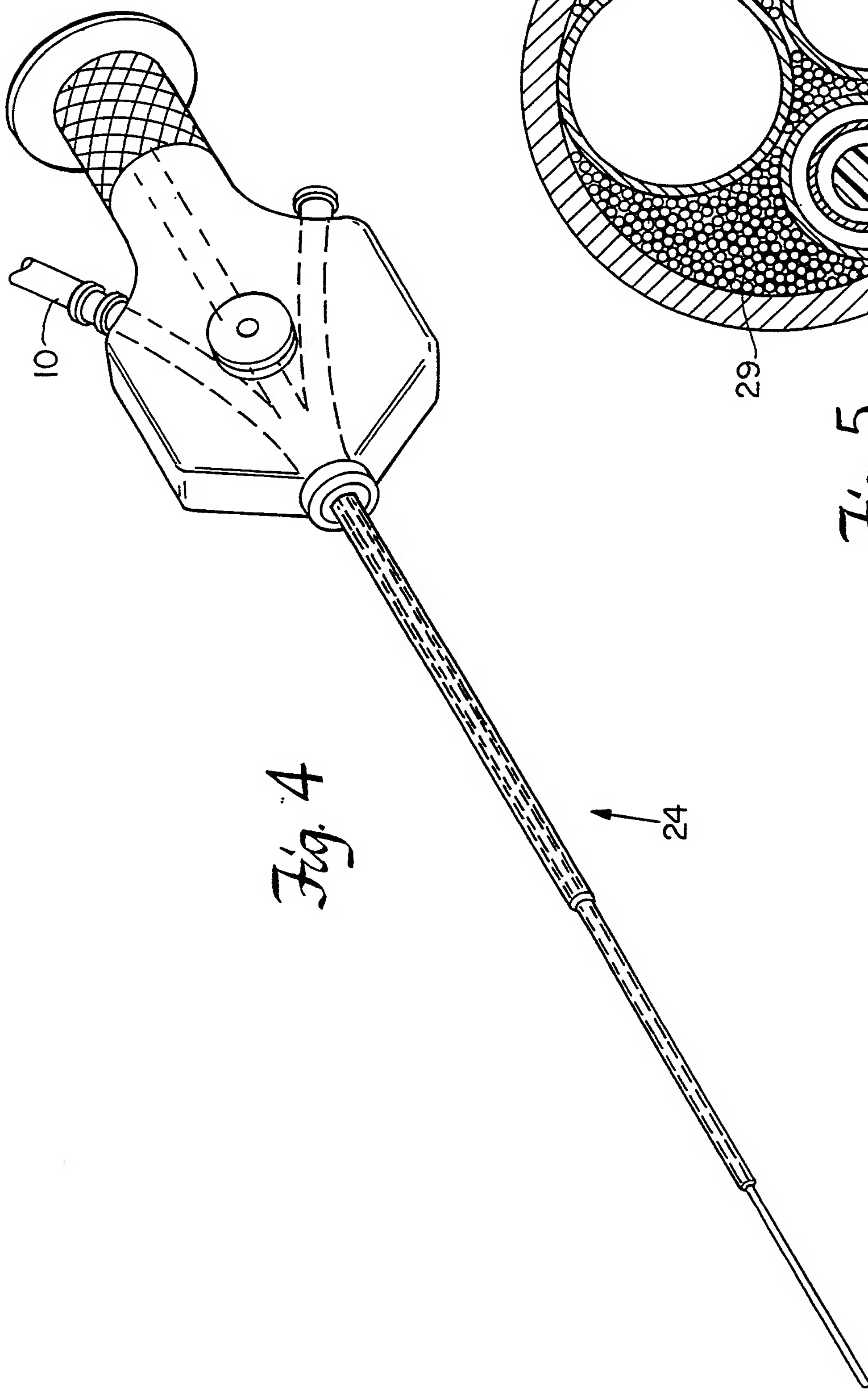

Fig. 4

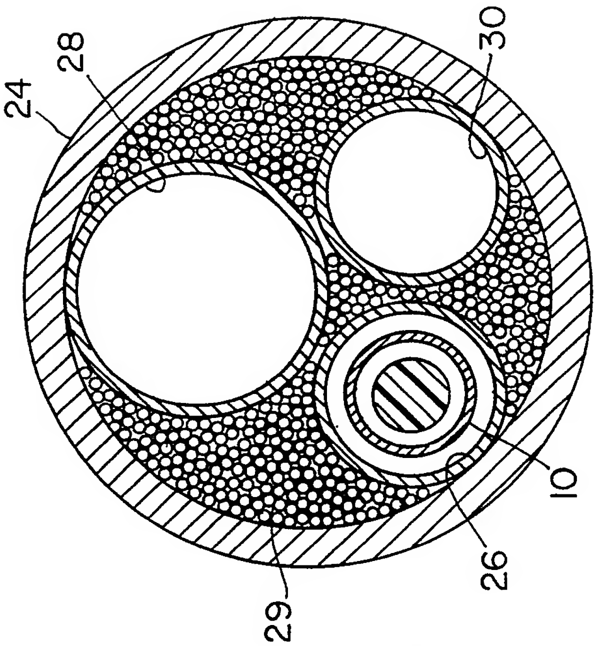

Fig. 5

INTERNATIONAL SEARCH REPORT

International Application No PCT/US 91/00143

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) [6]

According to International Patent Classification (IPC) or to both National Classification and IPC

IPC^5: A 61 B 17/22

II. FIELDS SEARCHED

Minimum Documentation Searched [7]

Classification System	Classification Symbols
IPC^5	A 61 B

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched [8]

III. DOCUMENTS CONSIDERED TO BE RELEVANT [9]

Category *	Citation of Document, [11] with Indication, where appropriate, of the relevant passages [12]	Relevant to Claim No. [13]
X	EP, A, 0268019 (WONDRAZEK et al.) 25 May 1988 see column 3, line 40 - column 4, line 2; column 4, lines 39-42; figures	1-5,9-14,19
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X,P	WO, A, 9009762 (ROSEN et al.) 7 September 1990 see page 4, lines 27-34; page 5, lines 15-20; page 6, lines 16-22; figures	1-3,5-9,12
A		11,13-18
	--	
A	DE, A, 3038445 (WILLNEFF) 27 May 1982 see claim 1; page 9, lines 9-15; figure 1	1,6,13,15
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	./.	

* Special categories of cited documents: [10]

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

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"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
23rd April 1991	10. 06. 91
International Searching Authority	**Signature of Authorized Officer**
EUROPEAN PATENT OFFICE	Danielle van der Haas

III. DOCUMENTS CONSIDERED TO BE RELEVANT (CONTINUED FROM THE SECOND SHEET)		
Category *	Citation of Document, [11] with indication, where appropriate, of the relevant passages	Relevant to Claim No.
A	GB, A, 2161079 (OINUMA et al.) 8 January 1986 see page 5, lines 69-75; figure 5	1
	--	
A	AT, A, 334515 (RICHARD WOLF) 25 January 1977 see page 3, lines 43-46	1

ANNEX TO THE INTERNATIONAL SEARCH REPORT ON INTERNATIONAL PATENT APPLICATION NO. US 9100143

SA 44083

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report.
The members are as contained in the European Patent Office EDP file on 04/06/91
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EP-A- 0268019	25-05-88	DE-A,C 3736953	26-05-88
		US-A- 4932954	12-06-90
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		JP-A- 61016735	24-01-86
		JP-B- 61058175	10-12-86
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		FR-A- 2567014	10-01-86
		US-A- 4605003	12-08-86
AT-A- 334515	25-01-76	None	

For more details about this annex : see Official Journal of the European Patent Office, No. 12/82